510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K060968

B. Purpose for Submission:

New Device

C. Measurand:

Prothrombin Time (PT)

Activated Partial Thromboplastin Time (APTT)

Fibrinogen

D. Type of Test:

Quantitative, mechanical and photo-optical

E. Applicant:

Wortham Laboratories, Inc.

F. Proprietary and Established Names:

Stasis 1 Coagulation Control (Normal)
Stasis 2 Coagulation Control (Abnormal)
Stasis 3 Coagulation Control (Abnormal)

Serathan-A PT Reagent
Serathan-B PT Reagent

Intrin-SI APTT Reagent
Intrin-EA APTT Reagent
Calcium Chloride Solution 0.02 M

Fibrinogen Control Plasma Normal
Fibrinogen Control Plasma Low
Fibrinogen Buffer
Thrombin Reagent

Fibrinogen Assay Set

Heparin Control Plasma Level 1
Heparin Control Plasma Level 2

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425, Plasma, Coagulation Control
   21 CFR 864.7750, Prothrombin Time Test
   21 CFR 864.7925, Activated Partial Thromboplastin Time
   21 CFR 864.7340, Fibrinogen Determination System

2. Classification:

   Class II

3. Product code:

   GIZ, Plasma, Control, Normal
   GGC, Plasma Control, Abnormal
   GGN, Plasma, Coagulation Control
   GJS, Test, Time, Prothrombin
   GFO, Activated, Test, Thromboplastin
   GIL Plasma, Fibrinogen Control
   KQJ, System, Fibrinogen Determination

4. Panel:

   81 (Hematology)

H. Intended Use:

1. Intended use(s):

   Stasis 1 Coagulation Control (Normal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Fibrinogen assays. It will yield PT, APTT, and Fibrinogen values in the normal range.

   Stasis 2 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the moderate abnormal range.

Stasis 3 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the strongly abnormal range.

Serathan-A PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-A is a highly sensitive thromboplastin reagent.

Serathan-B PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-B is a moderately sensitive thromboplastin reagent.

Intrin-EA APTT is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-EA reagent is sensitive to mild coagulopathies.

Intrin-SI is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-SI reagent is sensitive to heparin and lupus anticoagulant plasmas.

Calcium Chloride Solution 0.02 M ($CaCl_2$) is intended for quantitative use with ellagic acid (Intrin-EA) or silicone particulate activators (Intrin-SI) in performing the Activated Partial Thromboplastin Time (APTT) on citrated plasma.

Fibrinogen Plasma Controls Normal and Low are quantitative control plasma intended for use in the quality control of fibrinogen assays.

Fibrinogen Buffer is intended for use with fibrinogen controls for quantitative determine of fibrinogen in plasma.

Thrombin Reagent is intended for use in the quantitative determination of fibrinogen in plasma samples.

Fibrinogen Assay Set, containing a complete set of Normal Fibrinogen Control (200-400 mg/dl), Thrombin Reagent (100 IU/ml), and Fibrinogen Buffer, is intended for use in the quantitative determination of fibrinogen in plasma samples.

Heparin Control Level 1 and Level 2 are intended as a quality control of the Activated Partial Thromboplastin Time (APTT) during heparin monitoring.

2. Indication(s) for use:

   Same as above.

3. Special conditions for use statement(s):

   Not applicable.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

Stasis 1, 2, and **3** are liquid controls processed from human plasma collected with 3.2% sodium citrate anticoagulant, with stabilizers and buffers added. The product is supplied in 10 ml bottles.

Serathan-A and **Serathan-B** reagents are liquid products prepared from rabbit brain tissue, calcium, sodium azide, salts and stabilizers. The reagents are supplied in 20 ml bottles.

Intrin-SI reagent is prepared from rabbit brain phospholipids, kaolin, sodium azide, salts and stabilizers. The reagent is supplied in 10 ml bottles.

Intrin-EA reagent is prepared from rabbit brain phospholipids, ellagic acid, sodium azide, salts, and stabilizers. The reagent is supplied in 10ml bottles.

Calcium Chloride ($CaCl_2$) is composed of 0.222%M calcium chloride and 0.1% sodium azide. This reagent is supplied in 10 ml bottles

Fibrinogen Plasma Controls Normal and **Low** are liquid controls prepared from human plasma collected with 3.2% sodium citrate anticoagulant, with stabilizers and buffers. This control is supplied in 10 ml bottles.

Fibrinogen Buffer consists of 1.3% TAPSO Buffer, 0.1% sodium chloride, 0.1% sodium azide, and stabilizers; pH 7.35±0.05. This buffer is supplied in 100 ml bottles

Thrombin reagent is a liquid bovine thrombin containing 100 IU/ml, 0.1% sodium azide, and stabilizers. This reagent is supplied in 10ml bottles.

Fibrinogen Assay Set consists of: **Normal Fibrinogen Control** 200-400 mg/dl prepared from human plasma collected with 3.2% sodium citrate anticoagulant with stabilizers and buffers, **Thrombin Reagent** (100 IU/ml) which is liquid bovine thrombin, and **Fibrinogen Buffer** (TAPSO buffer in saline, pH 7.35±0.05, with 0.1% sodium azide as a preservative. This assay set contains 1 x 5 ml bottle of Normal

Fibrinogen Control, 1 x 5 ml bottle of Thrombin Reagent and 4 x 100 ml bottles of Fibrinogen Buffer.

Heparin Control Level 1 is a liquid preparation of citrated human plasma containing, 0.25 U/ml sodium heparin (derived from porcine intestine), sodium azide, stabilizers and buffers. The product is supplied in10 ml bottles.

Heparin Control Level 2 a liquid preparation of citrated human plasma containing, 0.35 U/ml sodium heparin (derived from porcine intestine), sodium azide, stabilizers and buffers. The product is supplied in 10 ml bottles.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Pacific Hemostasis Coagulation Control Level I, Pacific Hemostasis Coagulation Control Level II, Pacific Hemostasis Coagulation Control Level III

   Pacific Hemostasis Thromboplastin-DS Reagent, Pacific Hemostasis Thromboplastin-D Reagent

   Pacific Hemostasis APTT-LS, Pacific Hemostasis Kontact

   Pacific Hemostasis Fibrinogen Normal and Low Control, Pacific Hemostasis, Thrombin Reagent, Pacific Hemostasis Heparin Control I

2. Predicate 510(k) number(s):

   K984129, K984130, K984131
   K940082, K994100
   K891337, K023362
   K832520, K800826,
   K992278, K992279
   K970645

3. Comparison with predicate:

Similarities		
Item	***Stasis 1***	***Pacific Hemostasis Level I***
Intended Use	As a quality control to monitor performance of PT, APTT and Fibrinogen in the **normal** range.	Same
Expected Range (Mechanical)		
PT	11.5-11.8 sec	11.4-11.9 sec
APTT	29.3-29.7 sec	28.0-28.8 sec
Fibrinogen	301-313 g/dl	297-315 g/dl

Similarities		
Item	***Stasis 1***	***Pacific Hemostasis Level I***
Differences		
Composition	Liquid human citrated plasma	Lyophilized human citrated plasma
Stability	12 months at ≥ -2° C, 30 days at 2-8°C	35 months at 2-8°C, lyophilized, 8 hours at 2-8°C , rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Stasis 2***	***Pacific Hemostasis Level II***
Intended Use	As a quality control to monitor performance of PT and APTT in the **moderate abnormal** range.	Same
Expected Range (Mechanical)		
PT	19.9-20.3 sec	19.7-20.8 sec
APTT	54.9-56.6 sec	53.9-56.2 sec
Differences		
Composition	Liquid human citrated plasma	Lyophilized human citrated plasma
Stability	12 months at ≥ -2° C, 30 days at 2-8°C	35 months at 2-8°C, lyophilized, 8 hours at 2-8°C , rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Stasis 3***	***Pacific Hemostasis Level II***
Intended Use	As a quality control to monitor performance of PT and APTT in the **high abnormal** range.	Same
Expected Range (Mechanical)		
PT	32.0-33.0 sec	31.4-33.6 sec
APTT	69.4-71.5 sec	68.8-71.4
Differences		
Composition	Liquid human citrated plasma	Lyophilized human citrated plasma
Stability	12 months at ≥ -2° C 30 days at 2-8°C	35 months at 2-8°C, lyophilized 8 hours at 2-8°C , rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Serathan-A PT***	***Pacific Hemostasis Thromboplastin-DS***
Intended Use	For the quantitative determination of PT of coagulation abnormalities in the extrinsic pathway; **highly sensitive**	Same
Composition	Liquid Rabbit thromboplastin	Lyophilized Rabbit thromboplastin
International Sensitivity Index (ISI)	1.0-1.2	Same
Assay Factors	PT, Fibrinogen, Factors II, V, VII, X	Same
Differences		
Stability	12 months at ≥ -2° C 30 days at 2-8°C	30 months at 2-8°C, lyophilized 7 days at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Serathan-B PT***	***Pacific Hemostasis Thromboplastin-D***
Intended Use	For the quantitative determination of PT for coagulation abnormalities in the extrinsic pathway; **moderately sensitive**	Same
Composition	Liquid Rabbit thromboplastin	Lyophilized Rabbit thromboplastin
International Sensitivity Index (ISI)	1.5-1.7	Same
Assay Factors	PT, Fibrinogen, Factors II, V, VII, X	Same
Differences		
Stability	12 months at ≥ -2° C 30 days at 2-8°C	30 months at 2-8°C, lyophilized 7 days at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Intrin-EA APTT Reagent***	***Pacific Hemostasis APTT-LS***
Intended Use	For the quantitative determination of APTT for coagulation abnormalities in the intrinsic pathway; s**ensitive to mild coagulopathies.**	Same
Composition	Liquid Rabbit thromboplastin with ellagic acid activator	Same
Assay Factors	APTT, Heparin, Factors VIII, IX,XI,XII	Same

Similarities		
Item	***Intrin-EA APTT Reagent***	***Pacific Hemostasis APTT-LS***
Differences		
Stability	12 months at ≥ -2° C 30 days at 2-8°C	22 months at 2-8°C, lyophilized 30 days at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Intrin-SI APTT Reagent***	***Pacific Hemostasis Kontact***
Intended Use	For the quantitative determination of APTT for coagulation abnormalities in the intrinsic pathway; s**ensitive to heparin and lupus anticoagulant plasmas.**	Same
Composition	Liquid Rabbit thromboplastin with kaolin activator	Same
Assay Factors	APTT, Heparin, Factors VIII, IX,XI,XII	Same
Differences		
Stability	12 months at ≥ -2° C 30 days at 2-8°C	12 months at 2-8°C, lyophilized 30 days at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Fibrinogen Control Plasma (Normal and Low)***	***Pacific Hemostasis Fibrinogen Assay***
Intended Use	For use in the quality control of fibrinogen assays.	Same
Expected Range (Mechanical)		
Normal	301-313	297-315
Low	97-103	97-104
Differences		
Composition	Liquid human citrated plasma	Lyophilized human citrated plasma
Stability	12 months ≥ -2° C 30 days at 2-8°C	24 months at 2-8°C, lyophilized 16 days at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Thrombin Reagent)***	***Pacific Hemostasis Thrombin Reagent***
Intended Use	For thrombin to convert fibrinogen in the quantitative determination of fibrinogen in plasma samples.	Same
Expected Range (Mechanical)		
	118-120 IU/ml	118-120 IU/ml
Differences		
Composition	Liquid bovine thrombin	Lyophilized bovine thrombin
Stability	12 months at ≥ -2° C 30 days at 2-8°C	28 months at 2-8°C, lyophilized 1 day at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

Similarities		
Item	***Heparin Control Plasma (Level 1 and Level 2)***	***Pacific Hemostasis Heparin (Control Level 1 and Level 2)***
Intended Use	For use in the quality control of APTT during heparin monitoring, yielding slightly abnormal range for Level 1 (0.25 U/ml) and marked abnormal range for Level 2 (0.35 U/ml)	Same
Expected Range (Mechanical)		
Level 1	45.2-48.5 sec	44.8-49.1 sec
Level 2	62.4-64.6 sec	60.1-65.2 sec
Differences		
Composition	Liquid human citrated plasma with heparin	Lyophilized human citrated plasma with heparin
Stability	12 months at ≥ -2° C 30 days at 2-8°C	36 months at 2-8°C, lyophilized 8 hours at 2-8°C, rehydrated
Storage	≥ -2° C	2-8° C

K. Standard/Guidance Document Referenced (if applicable):

H47-A *One Stage Prothrombin Time (PT) Test and Activated Partial Activated Thromboplastin (APTT) Test; Approved Guideline*, NCCLS

H21-A3 *Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline; Third Edition,* NCCLS

H30-A2 *Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline - Second Edition,* NCCLS

WHO Expert Committee on Biological Standardization 28th Report: WHO Technical Series 610, World Health Organization, Geneva, pp. 14-15 and 45-51; 1977.

L. Test Principle:

Stasis 1 (Normal), Stasis 2 (Moderate Abnormal), and Stasis 3 (High Abnormal): The use of quality controls is essential for assuring quality in coagulation testing. Stasis 3 and a normal control, such as Stasis 1, are an integral part of a complete quality assurance program.

Serathan-A and Serathan-B reagents: The PT is used as a screen and quantitative test for coagulation factors in the extrinsic and common pathways. Patients with acquired or congenital disorders that reduce the activities of Fibrinogen and Factors II, V, VII, and X will be prolonged in this test. The PT is used to monitor oral anticoagulation therapy. The one step PT measures the clotting time of plasma after adding a source thromboplastin and calcium. The recalcification of plasma with thromboplastin generates activated FXa. FXa in turn activates Prothrombin, which converts fibrinogen to an insoluble fibrin clot.

Intrin-EA and Intrin-SI reagents: The APTT is an established tool as a quantitative test for the intrinsic coagulation factors. It is a simple versatile test which is sensitive to functional deficiencies of factors VIII, IX, XI, and XII. The APTT is performed by adding reagent containing a plasma activator and phospholipid to the test specimen.

Thrombin Control Normal and Low, Thrombin Reagent: The thrombin clotting time fibrinogen assay is based on the method described by Clauss. 1 In the presence of high concentrations of thrombin, the time required for clot formation in dilute plasma is inversely proportional to the fibrinogen concentrations.

Heparin Control Plasma Level 1 and 2: The anticoagulant heparin is used in the treatment of various thrombosis disorders, and for the prevention of thrombin formation during surgery. There are a number of assays available for the clinical laboratory to monitor heparin therapy. A critical component in these assays is the use of quality control plasmas.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Stasis 1 Control is formulated to have PT, APTT, and Fibrinogen values in the normal range. The reproducibility of three lot of the control, a run-run (n=180) singlicate assays, produced a coefficient of variations of < 1% for the PT, < 1% for the APTT, and < 1% for Fibrinogen assays. This study was performed on the BBL Fibrometer.

      Stasis 2 Control is formulated to have PT, APTT values in the moderate abnormal range. The reproducibility of three lots of the control, a run-run (n=180) singlicate assays, produced a coefficient of variations of < 1% for the

PT, < 1.5% for the APTT assays. This study was performed on the BBL Fibrometer.

Stasis 3 Control is formulated to have PT, APTT values in the strongly abnormal range. The reproducibility of three lots of the control, a run-run (n=180) singlicate assays, produced a coefficient of variations of < 1% for the PT, < 1.6% for the APTT assays. This study was performed on the BBL Fibrometer.

Serathan-A and Serathan-B: Both reagents were assayed by testing the reagent against three lots each of normal and abnormal control plasma, in singlicate assays, on the BBL Fibrometer. A summary of the results follow:

Serathan-A

	Level 1			Level 2			Level 3		
	n	run(sec)	% CV	n	run(sec)	% CV	n	run(sec)	% CV
Within-run	60	12.66	0.89%	60	36.45	1.09%	60	61.60	1.25%
Run-run	60	12.67	0.88%	60	36.47	.08%	60	61.13	1.28%

Serathan-B

	Level 1			Level 2			Level 3		
	n	run(sec)	% CV	n	run(sec)	% CV	n	run(sec)	% CV
Within-run	60	11.57	0.80%	60	21.17	1.27%	60	32.51	1.42%
Run-run	60	11.56	0.75%	60	21.13	1.22%	60	32.51	1.44%

Intrin-EA was assayed by testing the reagent against normal and abnormal control plasmas, in singlicate assays, on the BBL Fibrometer. A Summary of the results follows:

	Level 1			Level 2			Level 3		
	n	run(sec)	% CV	n	run(sec)	% CV	n	run(sec)	% CV
Within-run	60	29.01	0.51%	60	48.03	0.41%	60	67.74	0.73%
Run-run	60	29.03	0.60%	60	47.52	0.44%	60	67.74	0.71%

Intrin-SI was assayed by testing normal and abnormal plasmas on the BBL Fibrometer. A Summary of the results follows:

	Level 1			Level 2			Level 3		
	n	run(sec)	% CV	n	run(sec)	% CV	n	run(sec)	% CV
Within-run	60	29.51	0.29%	60	55.75	0.74%	60	70.49	0.75%
Run-run	60	29.51	0.29%	60	55.75	0.75%	60	70.49	0.75%

Fibrinogen Control Low plasma samples were tested on the BBL Fibrometer, yielding a within-run and run-run precision of 0.60% CV and 0.58% CV, respectively.

Fibrinogen Control Normal plasma samples were tested on the BBL Fibrometer, yielding a within-run and run-run precision of 0.56% CV and 0.57% CV, respectively.

Heparin Control Level 1 Plasma as abnormal APTT control, within-run precision studies performed on the BBL Fibrometer using Intrin-SI reagent yielded CV's of 1.82 %, and a 1.77% CV for run-run assays.

Heparin Control Level 2 Plasma as abnormal APTT control, within-run precision studies performed on the BBL Fibrometer using Intrin-SI reagent yielded CV's of 1.92 %, and a 1.81% CV for run-run assays.

Thrombin Reagent: Precision of the Normal and Low Fibrinogen Control result is dependent on many factors, such as the instrument, technique and the reagent used. A 1:6 and 1:8 dilutions of 3 lots of the Normal and Low Fibrinogen Control respectively, were made and assayed in singlicate on the BBL Fibrometer. A summary of the results follow:

Control	**n**	**within-run**	**n**	**run-run**
Normal	60	0.56% CV	180	0.57% CV
Low	60	0.60% CV	180	0.58% CV

b. Linearity/assay reportable range:

Serathan-A Reportable Range/Linearity: A linearity study, assayed on the BBL Fibrometer, of Intrin-EA to measure warfarin in 18 plasma samples of 0-5 U/ml, yielded a linearity range of 12.1 –41.9 seconds.

Serathan-B reagents Reportable Range/Linearity: A linearity study, assayed on the BBL Fibrometer, to measure warfarin in 18 plasma samples of 0-5 U/ml, yielded a linearity range of 11.6 –36.2 seconds.

Intrin-EA A **Reportable Range/Linearity:** linearity study, assayed on the BBL Fibrometer, of Intrin-EA to measure heparin in 18 plasma samples of 0-5 U/ml, yielded a linearity range of 29.0 –70.7 seconds.

Intrin-SI Reportable Range/Linearity: A linearity study, assayed on the BBL Fibrometer, of Intrin-SI to measure heparin in18 plasma samples of 0-5 U/ml, yielded a linearity range of 29.8 - 106.3 seconds.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Expected Values:

Stasis Control 1, 2, 3
When all levels of Stasis controls were evaluated on the BBL Fibrometer, the following results were obtained:

	Serathan-B (ISI=1.58)	**Serathan-A (ISI=1.20)**
Stasis 1	11.5-11.9	12.4-12.8 sec
Stasis 2	20.4-22.0	31.6-33.4 sec
Stasis 3	31.6-33.4 sec	60.7-62.3 sec

	Intrin-SI	Intrin-EA
Stasis 1	29.3-29.7 0	28.6-29.4 sec
Stasis 2	55.0-56.6 sec	46.0-47.0 sec
Stasis 3	69.4-71.6 sec	63.8-65.8 sec
	Fibrinogen, Normal	
Stasis 1	299-303 mg/dl	

Fibrinogen Control Low
Three lots were evaluated in singlicate on the BBL Fibrometer (n=180), the run-run mean fibrinogen level of 99 mg/dl and a ± 2SD range of 98-100 mg/dl. Actual values recovered depend on the instrument and reagent used.

Fibrinogen Control Normal
Three lots were evaluated in singlicate on the BBL Fibrometer (n=180), the run-run mean fibrinogen level was 301 mg/dl and at ± 2SD range of 300-302 mg/dl Actual values recovered depend on the instrument and reagent used.

Heparin Control Plasma Level 1 was assayed on the BBL Fibrometer produced a mean APTT clotting time of 46.9 seconds and a ± 2SD range of 45.1-48.7 seconds.

Heparin Control Plasma Level 2 was assayed on the BBL Fibrometer produced a mean APTT clotting time of 63.5 seconds and a ± 2SD range of 61.2-65.8 seconds.

Stability: A Real Time Stability study for all coagulation controls and reagents was performed for 30 days at -2^{o}C and 4^{o}C. Results showed not loss of activity. Real time studies will be on going.

d. Detection limit:

Not Applicable.

e. Analytical specificity:

Not Applicable.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Serathan-A and Serathan-B was tested against the predicate with 120 adult

normal and coumadin patient samples, in singlicate assay.
Results:

Serathan A	r = 0.999	y = 0.948x +0.620
Serathan-B	r = 0.996	y = 0.989x + 0.039

Intrin-EA and **Intrin- SI: S**tudies were performed against another thromboplastin reagent by performing APTT testing on 120 adult normal and heparinized patient samples, and 10 lupus anticoagulant plasma samples in singlicate assay, on the BBL Fibrometer.

Results:

Intrin-EA	r = 0.996	y = 1.022x +1.293
Lupus Study	r = 0.979	y = 1.037 x- 4.363
Intrin-SI	r = 0.998	y = 1.032x + 0.15
Lupus Study	r = 0.844	y = 1.033 x- 4.76

b. Matrix comparison:

Not Applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

*b. Clinical specificity**:***

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable.

4. Clinical cut-off**:**

Not Applicable.

5. Expected values/Reference range:

Serathan-B was evaluated on a normal population, the following results were obtained:

Instrument	PT Mean (sec)	Range (± 2SD)	N
ACL Advance	11.5	10.9 –12.1	60

Serathan-A was evaluated on a normal population, the following results were obtained:

Instrument	PT Mean (sec)	Range (± 2SD)	N
ACL Advance	12.1	11.9 –12.3	60

Intrin-EA was evaluated on 60 normal adult patients using the BBL Fibrometer, the following results were obtained.

	PT Mean (sec)	Range (± 2SD)	N
Photo-optical	29.0	28.7 –29.3	60
Mechanical	29.0	28.5 –29.5	60

These values should only be used as a guideline. Each laboratory should establish a Normal Reference Range

Intrin-SI was evaluated on 60 normal adult patients, the following results were obtained.

	PT Mean (sec)	Range (± 2SD)	N
Photo-optical	29.5	29.3 –29.6	60
Mechanical	29.5	29.3 –29.6	60

Thrombin Reagent

Laboratories should establish a normal control interval for fibrinogen measurement. The referenced normal control is 200-400 mg/dl.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.